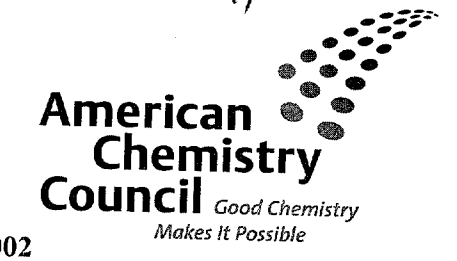
8EHQ-1002-15207

MR# 62541

8EHQ-02-15207



Via Hand Delivery
DATE: October 4, 2002

Document Control Officer
Mail Stop TS-7407
Office Pollution Prevention and Toxics
U.S. Environmental Protection Agency
EPA East Building, Room 6428
1201 Constitution Avenue, N.W.
Washington, D.C. 20004-3302

Contain NO CBI

RECEIVED
OPPT CBIC
2002 OCT -7 AM 6:17

88030000002

Attn: TSCA 8(e)

Re: TSCA Section 8(e) Reporting Notification for Methyl Bromide

Dear Sir or Madam:

The American Chemistry Council (ACC) submits the following information concerning methyl bromide (CAS No. 74-83-9). This information is submitted on behalf of the members of the Methyl Bromide Industry Panel (MBIP), which consists of Albemarle Corporation, Ameribrom, Inc., Great Lakes Chemical Corporation, and TriCal, Inc. Methyl bromide is registered as pesticide under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), but a small amount is used as a chemical feedstock in the production of other commercial chemicals.

The National Cancer Institute is engaged in an on-going, long-term survey of farmers, applicators and other persons using pesticides on a regular basis (the "National Agricultural Health Study"). The survey began in 1993 with the purpose of examining the possible connection between pesticide use and the incidence of cancer. Information was gathered from approximately 90,000 people located in North Carolina and Iowa consisting of about 52,000 farmers, approximately 30,000 of their spouses, and almost 5,000 commercial applicators.

RECEIVED
OPPT CBIC
2002 OCT 16 PM 1:14

In mid-August 2002, a trade publication called the "Chemical Marketing Reporter" ran an article about a public meeting in which the study's principal investigator, Dr. Michael Alavanja (NCI), reported preliminary findings from the National Agricultural Health Study concerning methyl bromide. On September 13, 2002, representatives of the MBIP contacted Dr. Alavanja to find out if the news article was accurate and obtain information about his remarks.

According to Dr. Alavanja, early results from the National Agricultural Health Study indicate an increased risk of prostrate cancer among persons participating in the survey that reported high use levels of certain pesticides (including methyl bromide) compared to the general population. A familial history of prostrate cancer appears to increase the risk and these factors may be synergistic. Because this possible link was not one of the objectives of the original survey and there are no other epidemiological or toxicological studies suggesting such a link, further study and analysis will be undertaken by NCI to validate this preliminary information. Subsequent to these discussions, the NCI provided the MBIP with an "abstract" of the study that does not discuss the preliminary findings for methyl bromide. (A copy of this abstract is enclosed.) Thus, it

remains unclear whether the preliminary findings on methyl bromide reported by Dr. Alavanja on September 13 are valid.

The MBIP does not know when a final report on this issue will be available. Validated findings would be subject to EPA's FIFRA Section 6(a)(2) adverse effects reporting policy for pesticides. The MBIP's obligation to report such findings would not run until 30 days after the final analyses were made available to it, and would cease if the NCI published the final results before that period ran.[1] Information submitted to EPA under FIFRA Section 6(a)(2) is not subject to TSCA 8(e) reporting.[2] However, health effects information subject to TSCA 8(e) must be submitted to EPA within 15 business days from the date on which it is obtained.[3] Information submitted to EPA under TSCA 8(e) is not subject to duplicative reporting under FIFRA § 6(a)(2).

Because methyl bromide is used as a non-pesticide, chemical feedstock, and the reporting requirements of FIFRA Section 6(a)(2) and TSCA 8(e) are not consistent under the circumstances presented, the MBIP is reporting the preliminary information supplied by Dr. Alavanja and NCI to the TSCA 8(e) Coordinator at this time to ensure the fullest possible compliance with both policies.

The MBIP reserves the right to supplement the information presented in this submission once final, validated analyses are made available from NCI.

If you have questions concerning this report, please call me at (703) 741-5635.

Sincerely,

Susan A. Lewis/JHS

Susan A. Lewis, Ph.D.
Manager, MBIP

Enclosure
cc: MBIP Members

[1] *See* 40 C.F.R. §§ 159.155(a)(3), 159.158(b)(3) and 159.170.
[2] *See* 40 C.F.R. § 159.158(b)(2).
[3] *See* EPA's TSCA 8(e) Statement of Interpretation and Enforcement Policy, 52 Fed. Reg. 1112 (March 16, 1978).

AGRICULTURAL HEALTH STUDY COORDINATING CENTER WESTAT, 1650 RESEARCH BLVD., ROCKVILLE MD 20850

USE OF AGRICULTURAL PESTICIDES AND PROSTATE CANCER RISK IN THE AGRICULTURAL HEALTH STUDY COHORT

Michael C. R. Alavanja, Claudine Samanic, Mustafa Dosemeci, Jay Lubin, Robert Tarone, Charles F. Lynch, Charles Knott, Jane A. Hoppin, Joseph Barker, Joseph Coble, Dale P. Sandler, Aaron Blair

ABSTRACT

The role of specific agricultural chemicals in relation to prostate cancer risk has not been firmly established due to the lack of precise exposure data. We examined the relationship between 45 common agricultural pesticides and prostate cancer incidence in a prospective cohort study of 55,332 male pesticide applicators from Iowa and North Carolina with no prior history of prostate cancer. Data were collected by means of self-administered questionnaires completed at enrollment (1993-1997). Cancer incidence was determined through population-based cancer registries from enrollment through December 31,1999. A prostate cancer standardized incidence ratio (SIR) was computed as were odds ratios for individual pesticides and for pesticide use patterns identified through factor analysis. A prostate cancer SIR of 1.18 (95% CI, 1.09-1.28) was observed for the cohort. Factor analysis showed that use of chlorinated pesticides among applicators currently over 50 years of age was significantly associated with prostate cancer risk (p=0.005). Significant interaction odds ratios were observed between specific pesticides (butylate, chlorpyrifos, coumaphos, fonofos, permethrin, phorate) a family history of prostate cancer and prostate cancer risk. Pesticide applicators have a small but significantly higher rate of prostate cancer than the general population. Findings for use of chlorinated pesticides, methyl bromide, and pesticide-family history interactions are novel and need to be confirmed.